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In The Supreme Court of the United States

APOTEX, INC. AND APOTEX CORP.,
Petitioners,

v.

SANOFI-SYNTHELABO, SANOFI-SYNTHELABO INC., and BRISTOL-MYERS SQUIBB SANOFI PHARMACEUTICALS HOLDING PARTNERSHIP,
Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

MOTION FOR LEAVE TO FILE BRIEF *AMICI CURIAE* AND BRIEF OF AARP, PATIENTS NOT PATENTS, AND THE PUBLIC PATENT FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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MOTION FOR LEAVE TO FILE BRIEF *AMICI CURIAE*

Pursuant to Rule 37.2(b) of the Rules of the Supreme Court of the United States, *Amici* AARP, Patients Not Patents, and the Public Patent Foundation hereby request leave to file the accompanying *amicus curiae* brief. This brief is submitted in support of the petition for writ of certiorari to the Court of Appeals for the Federal Circuit. Petitioners Apotex, Inc. and Apotex Corp. have consented to the filing of this brief. Respondents Sanofi-Synthelabo, Sanofi-Synthelabo Inc., and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership received timely notice but have not consented.

INTEREST OF *AMICI CURIAE*

Amicus AARP is a nonpartisan, nonprofit membership organization addressing the needs and interests of older Americans. AARP works at the state and federal levels for legislation beneficial to its constituents, and believes that this case poses an important question for consumer access to generic drugs.

Amicus Patients Not Patents, Inc. ("PNP") is a 501(c)(3) nonprofit organization based in Washington, D.C., dedicated to ensuring greater access to healthcare. PNP believes this case could affect the cost and availability of many important medicines.

Amicus Public Patent Foundation ("PUBPAT") at Benjamin N. Cardozo School of Law is a not-for-profit legal services organization representing the public interest in the patent system, and supports

this petition to maintain patent policy within the ambit of this Court's decisions.

REASONS FOR GRANTING MOTION

Amici Curiae respectfully submit this brief in support of petitioners Apotex, Inc. and Apotex Corp. (collectively, "Apotex"), encouraging the grant of a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit, because that judgment stems from the application of an "obvious to try" approach that is inconsistent with this Court's approach to obviousness in *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007), and with both health and patent policy. Allowing patents on obvious improvements to existing drugs and medical treatments burdens the public with excessive health care costs, delays generic entry longer than intended by Congress, and dulls incentives for real innovation in medical care.

August 27, 2009

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INTEREST OF THE *AMICI CURIAE*[1]

Amici Curiae AARP, Patients Not Patents, and the Public Patent Foundation respectfully submit this brief in support of petitioners Apotex, Inc. and Apotex Corp. (collectively, "Apotex"), encouraging the grant of a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit, because that judgment stems from the application of an "obvious to try" approach that is inconsistent with this Court's approach to obviousness in *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007), and with both health and patent policy. Allowing patents on obvious improvements to existing drugs and medical treatments burdens the public with excessive health care costs, delays generic entry longer than intended by Congress, and dulls incentives for real innovation in medical care.

Amicus AARP is a nonpartisan, nonprofit membership organization of nearly 40 million persons age 50 or older. It is dedicated to addressing the needs and interests of older Americans. As the country's largest membership organization, AARP has a long history of advocating for access to affordable health care and for controlling costs without compromising quality. Affordable prescription

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[1] No counsel for a party authored this brief in whole or in part and no person, other than *amici*, their members, or counsel made a monetary contribution to the preparation or submission of this brief. Counsel of record for all parties received notice at least 10 days prior to the due date of the amici's intention to file this brief. Petitioners have consented to the filing of this brief. A Motion For Leave to File *Amici's* Brief is included herein.

medication is particularly important to the older population which, because of its higher rates of chronic and serious health conditions, has the highest rate of prescription drug use. Persons over sixty-five, although only thirteen percent of the population, account for thirty-four percent of all prescriptions dispensed and forty-two cents of every dollar spent on prescription drugs. Families USA, Cost Overdose: Growth in Drug Spending for the Elderly, 1992-2010 at 2 (July 2000). Since prescription drug spending has skyrocketed over the last decade and a half, and national health expenditures on prescription drugs have quadrupled, AARP advocates for broader access to prescription drugs and lower prescription drug costs for consumers. To that end, AARP works at the state and national levels for laws and policies that will bring more generic competition to the marketplace. *See e.g.*, AARP, Rx Watchdog Report, April 2009, Vol. 6, Issue 3, available at http://assets.aarp.org/www.aarp.org_/cs/health/rx_watchdog_apr09.pdf.

Amicus Patients Not Patents, Inc. ("PNP") is a 501(c)(3) nonprofit organization based in Washington, D.C. PNP is committed to ensuring access to healthcare through litigation, advocacy and education. PNP is organized around the principle that medical treatment should not be denied or restricted because of the existence of patents or other intellectual property barriers. PNP has successfully challenged the validity of patents on drugs owned by pharmaceutical companies through administrative proceedings at the U.S Patent and Trademark Office. PNP supports a grant of certiorari in this case because the outcome will affect the cost and availability

of the drug clopidogrel and of other important medicines.

Amicus Public Patent Foundation ("PUBPAT") at Benjamin N. Cardozo School of Law is a not-for-profit legal services organization that represents the public interest in the patent system, and most particularly the public interest in protecting against the harms caused by undeserved patents and unsound patent policy. PUBPAT provides the general public and specific persons or entities otherwise deprived of access to the patent system with representation, advocacy, and education. PUBPAT has argued for sound patent policy before this Court, the Court of Appeals for the Federal Circuit, various district courts, the United States House of Representatives, the United States Patent and Trademark Office (USPTO), the United Nations, the European Union Parliament, and other judicial, governmental and political bodies. PUBPAT has also requested that the USPTO re-examine specifically identified undeserved patents causing significant harm to the public. The USPTO has granted each such request. These accomplishments have established PUBPAT as a leading provider of public service patent legal services and one of the loudest voices advocating for comprehensive patent reform. PUBPAT supports this petition for certiorari because of its interest in ensuring that the obviousness bar to patentability is maintained at a proper level consistent with *KSR, Graham v. John Deere Co.*, 383 U.S. 1 (1966), and this Court's other decisions.

REASONS FOR GRANTING THE WRIT

I. THE FEDERAL CIRCUIT'S RELIANCE ON "UNEXPECTED RESULTS" TO HOLD PATENT CLAIMS NONOBVIOUS EVEN WHEN THEY RESULT FROM "OBVIOUS TO TRY" RESEARCH IS INCOMPATIBLE WITH THIS COURT'S OPINION IN *KSR*, CONTRARY TO STATUTE, AND INCONSISTENT WITH PATENT POLICY

As this Court reaffirmed only two years ago, the nonobviousness requirement is intended to ensure that "the results of ordinary innovation are not the subject of exclusive rights under the patent laws." *KSR v. Teleflex,* 550 U.S. 398, 427 (2007). Patents are awarded as "an inducement, to bring forth new knowledge." *Graham v. John Deere Co.*, 383 U.S. 1, 9 (1966). Thus, patents granted on "advances that would occur in the ordinary course without real innovation retard[] progress," *KSR*, 550 U.S. at 419, and impose the costs of exclusivity on the public needlessly. When unnecessary patent protection delays the introduction of generic drugs, the burden on the public is not only financial; there are dire implications for those suffering from disease and other health problems. Therefore it is particularly important that the lower courts consistently and correctly apply the patentability standard set out in the statute and in this Court's precedents.

To distinguish inventions that would be made in the ordinary course from those requiring a patent incentive, section 103 of the Patent Act requires that obviousness be evaluated according to the perspective of a "person having ordinary skill in the art"

("PHOSITA") and that that perspective be applied "at the time the invention was made." 35 U.S.C. § 103. Importantly, "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." 550 U.S. at 421.

Both this Court and the Federal Circuit have long recognized that it is important to focus on the state of the art at the time an invention was made so as to avoid the hindsight bias that may result from an ex post perspective on the invention. *KSR*, 550 U.S. at 421; *Graham*, 383 U.S. at 36 (1966); *In re Kahn*, 441 F.3d 997, 986 (Fed. Cir. 2006); *Para-Ordnance Mfg. v. SGS Importers Int'l*, 73 F.3d 1085, 1087-88 (Fed. Cir. 1995); *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050-51 (Fed. Cir. 1988); *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1551–53 (Fed. Cir. 1983). In fact, the Federal Circuit's "teaching, suggestion, or motivation to combine" test was an attempt to combat the propensity to underestimate the nonobviousness of inventions that appear simple once they have been made. *KSR*, 550 U.S. at 418–19; *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006); *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). Though the Federal Circuit's rigid application of the test was an erroneous means to deal with the risk of hindsight bias, *KSR*, 550 U.S. at 419, this Court acknowledged the concern that "[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning." *Id.* at 421.

Though the Federal Circuit recognizes the danger that a nonobvious invention might appear

obvious in retrospect, its obviousness doctrine ignores the complementary danger that an *obvious* invention might appear *nonobvious* in retrospect when desirable properties of the invention are revealed only after the fact. There are numerous situations, particularly in the pharmaceutical and chemical arenas, in which the specific outcome of a particular research direction is not predictable in advance. In many of these cases it is nonetheless perfectly clear to a person having ordinary skill in the art both how to proceed and that the research is likely to produce worthwhile results. In other words, it may be "obvious to try" a specific research path in light of the reasonable probability of a useful outcome, even when the exact parameters of the outcome are not known in advance. *In re O'Farrell*, 853 F.2d 894, 903–04 (Fed. Cir. 1988).

In the instant case, for example, there was no way to predict exactly how the properties of the right and left enantiomers of PCR4099 would differ in toxicity and effectiveness, yet it was well known to the PHOSITA that there were likely to be differences of pharmaceutical significance and that there were well-known techniques available for separating the enantiomers. Thus, even though the PHOSITA would not have known just how good a blood thinner clopidogrel would turn out to be, there were strong incentives to pursue the well-defined research path to separate the enantiomers and determine their differential properties. The surprisingly good properties of clopidogrel would thus have been uncovered in the ordinary course of the PHOSITA's research.

As this Court recognized in *KSR*, "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." 550 U.S. at 421. Indeed, the Federal Circuit long ago recognized this possibility, *O'Farrell*, 853 F.2d at 903-04, as did this Court, *Mandel Bros., Inc. v. Wallace*, 335 U.S. 291, 296 (1948) ("skillful experiments in a laboratory, in cases where the principles of the investigations are well known, and the achievement of the desired end requires routine work rather than imagination, do not involve invention"). Prior to *KSR*, however, a line of Federal Circuit cases had lost track of this reality, stating categorically that an invention could not be proved obvious by demonstrating that it was "obvious to try." *In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995), for example, opined that "obvious to try has long been held not to constitute obviousness" and that "[a] general incentive does not make obvious a particular result, nor does the existence of techniques by which those efforts can be carried out." *Id.*

In *KSR*, this Court repudiated this categorical approach, making it clear that there are situations in which the fact that it is "obvious to try" a particular development can demonstrate obviousness under the Patent Act. 550 U.S. at 421. Since *KSR* was decided, however, confusion has reigned in the Federal Circuit's "obvious to try" jurisprudence, as detailed in the Petition for Certiorari in this case. Opinions have continued to focus, incorrectly, on an ex post analysis of the properties of a claimed invention, rather than

on whether the invention would have been made in the ordinary course without the need for a patent incentive. *See, e.g., Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1351 (Fed. Cir. 2008); *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1361–62 (Fed. Cir. 2007) (discussing how Alphapharm's obviousness argument would fail on either of two grounds, one that claimed compound possessed unexpected qualities post-modification). In this case, the Federal Circuit and district courts relied heavily on the "unexpected and unpredictable properties of clopidogrel [the right-handed enantiomer]" in holding that the separated enantiomer was nonobvious. Pet. App. at 27a–28a, 109a, 111a. .

As demonstrated in the opinion in this case, the Federal Circuit routinely relies on unexpected results to rebut what it calls a "prima facie case of obviousness." Pet. App. at 105a–106a. This focus on unanticipated properties of an invention directly conflicts with the statutory requirement that obviousness be evaluated at the time of invention and with this Court's recognition in *KSR* that the patent laws are not intended to award exclusive rights to "the results of ordinary innovation." 550 U.S. at 427.

Patents are intended to provide incentives for inventive efforts. *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980); *Graham*, 383 U.S. at 687-88. The nonobviousness requirement helps to ensure that patents are available only when they are needed to provide such incentives. *KSR*, 550 U.S. at 427. Results that are unanticipated can have no effect on such ex ante incentives and thus should play no part in evaluating obviousness. If a particular course of

action is sufficiently motivated by "design need or market pressure" and there is a reasonable expectation of a successful outcome to the project, the fact that the results of the project turn out to be even better than the PHOSITA would have anticipated is simply immaterial to the evaluation of obviousness "at the time of the invention." 35 U.S.C. § 103.

The inquiry into whether a particular research path would have been obvious to try in light of "ordinary skill and common sense," *KSR*, 550 U.S. at 421, does not run afoul of the statutory caveat that "patentability shall not be negatived by the manner in which the invention was made," 35 U.S.C. § 103, regardless of whether the claimed invention has unexpected properties. The question is whether the research would have been obvious to try *to the PHOSITA* at the time of the invention. The manner in which a particular patent applicant produced the claimed invention is irrelevant.

In this case, Apotex correctly argued that "the correct inquiry is not whether the results obtained with the separated enantiomer were unexpected, but whether it would have been obvious to separate and test the enantiomers, based on the general knowledge that enantiomers can exhibit different properties." Pet. App. at 27a-28a. The Federal Circuit mistakenly rejected this argument in favor of a focus on the irrelevant determination that "[t]he evidence at trial well supported the finding that the result of this separation of enantiomers was unpredictable." *Id.* at 30a. This emphasis on an ex post facto inquiry into the outcome of the research, rather than on the need for patent incentives to engage in it, has alway

been inconsistent with the statutory focus on the time of the invention. After this Court's opinion in *KSR*, the approach is untenable.

II. THE HINDSIGHT APPROACH TAKEN TO THE "OBVIOUS TO TRY" ISSUE IN PHARMACEUTICAL CASES HAS GRAVE CONSEQUENCES FOR MILLIONS OF PERSONS.

The non-obviousness standard for patent approval is crucial in the context of pharmaceuticals and consumer access to life-saving drugs. Relying on the unpredictability of the results to award patents for the fruit of obvious research paths will lead to unwarranted patent protection for obvious pharmaceutical advances, sacrificing access to important medicines without a compensating increase in innovation. Because results that can be characterized as unpredictable in some way are so common in the pharmaceutical field, such a hindsight-driven analysis vastly and unnecessarily expands the scope of patentability, directly harming consumers through reduced access, higher prices, and restrained competition. This excessive patenting also leads to patients foregoing needed medical care to save money, damaging the public health of the nation.

Generic drugs cost, on average, 70% less than branded drugs, and yielded $734 billion dollars in savings to consumers between 1998 and 2009.[2]

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[2] *See* Kathleen Jaeger, President & Chief Executive Officer, Generic Pharm. Ass'n. Testimony Before the U.S. House of Representatives' Energy and Commerce Committee (May 18, 2005) *available at* www.gphaonline.org/resources/2009/02/12/

Studies have shown that Medicare recipients in particular could save substantial sums by using more generic drugs.[3] These statistics demonstrate the huge financial stakes at issue for consumers regarding the availability of generic pharmaceuticals. Even more significantly, research consistently has shown that patients respond to higher drug prices by reducing drug consumption: *i.e.*, "financial barriers compel older Americans to forgo needed drug treatment."[4] Further exacerbating these realities is the fact that between 2002 and 2007 annual increases in prices for branded pharmaceuticals have outpaced inflation by a factor as high as 3.[5] When drugs are unnecessarily expensive, the public health is undermined.

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gpha-testimony-house-energy-and-commerce-committee-generic-utilization; Press Release, Generic Pharm. Ass'n, Generic Pharmaceuticals saved $734 Billion over Last Decade (May 7, 2009) *available at* www.gphaonline.org/media/press-releases/2009/generic-pharmaceuticals-saved-734-billion-over-last-decade.

[3] *See* More Studies Find More Savings if Seniors Use Generic Drugs, SeniorJournal.com (March 3, 2006) *available at* http://www.seniorjournal.com/NEWS/MedicareDrugCards/6-03-03-MoreStudiesFind.htm.

[4] Jan Blustein, *Drug Coverage and Drug Purchases by Medicare Beneficiaries with Hypertension*, 19 Health Affairs 219, 228 (2000) *available at* http://content.healthaffairs.org/cgi/reprint19/2/219; Dana Gelb Safranet al., Prescription Drug Coverage and Seniors: Findings from a 2003 Survey, Health Affairs (Web Exclusive) 157-58 (Apr. 19, 2005) *available at* http://content.healthaffairs.org/cgi/reprint/hlthaff.w5.152v1.

[5] David J. Gross et al., AARP Public Policy Institute, *Rx Watchdog Report: Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Medicare Beneficiaries 2002 to 2007* at iv (March 2008) *available at* http://assets.aarp.org/

The "obvious to try" doctrine at issue in this case is particularly important because pharmaceutical companies have increasingly used patents on incremental modifications or reformulations of existing drugs to extend their market exclusivity beyond the generous protections already available to them via patent protection on the basic drug, patent term extensions under the Hatch-Waxman Act, and data exclusivity periods provided by the FDA.[6] For example, more than one-third of products launched from 2002 to 2005 by the top fifty pharmaceutical manufacturers were reformulations of drugs already under patent, for which the "obvious to try" issue has particular salience. Dennis Kvesic, *Product Life Cycle Management: Marketing Strategies for the Pharmaceutical Industry*, 8 J. of Med. Mktg. 293, 296 (Sep. 1, 2008). This problem has engendered high-profile antitrust litigation accusing pharmaceutical companies of attempting to defeat generic penetration through anticompetitive manipulations of drug

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rgcenter/health/2008_05_watchdog_q407.pdf.

[6] *See* Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 Colum. L. Rev. 1471 (2008) (analyzing tactics used by pharmaceutical companies to extend product life by using reformulations of previously existing drugs); Herbert Hovenkamp et al., IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law § 12.5 (Supp. 2007) (same); Jon Leibowitz, Chairman, Fed. Trade Comm'n, "Pay for Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers Wallets, and Help Pay for Health Care Reform (The $35 Billion Solution) (June 23, 2009) *available at* http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf (describing problems caused by reverse payment settlements to keep generic drugs off the market).

formulations. *See Abbot Labs v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006).

When such a large fraction of "new" drugs hitting the market are reformulations of previously launched drugs, the Federal Circuit's erroneous application of the obvious to try doctrine leads directly to consumers foregoing needed medical attention and over-paying for health care.

These uses of patents on incremental and "obvious to try" advances, known to critics as "evergreening," Mark A. Lemley and Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U.L. Rev. 63, 82-83 (2004) and promoted by marketers as "product life cycle management,"[7] are attempts to game the system to provide windfall profits to pharmaceutical patent holders at the expense of the public health. The failure of some Federal Circuit panels to follow *KSR*'s directive that the obviousness requirement must provide incentives for innovation over and above what would occur in the ordinary course of a competitive marketplace, 550 U.S. at 417, will only lead to more gamesmanship on the part of patent owners.

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[7] *See, e.g.*, Dennis Z. Kvesic, *Product Lifecycle Management: Marketing Strategies for the Pharmaceutical* Industry, 8 J. Med. Mktg. 293 (2008) (describing successful use of secondary patents to extend profit timeline of drugs soon to expire); M. Burton & K. Sloper, *The Art of Using Secondary Patents to Improve Protection*, 3 Int'l J. of Med. Mktg. 226 (2003) (same); M. Agrawal & N. Thakkar, *Surviving Patent Expiration: Strategies for Marketing Pharmaceutical Products*, 6 J. Prod. & Brand Mgmt. 305 (1997) (same).

III. THIS CASE IS AN EXCELLENT VEHICLE FOR CLARIFYING THAT OBVIOUSNESS SHOULD BE EVALUATED WITHOUT ENGAGING IN AN EX POST INQUIRY INTO THE SPECIFIC UNPREDICTABLE OUTCOME OF AN OBVIOUS INVENTIVE ENDEAVOR.

This case is an excellent vehicle for this Court's consideration of the "obvious to try" issue. The particular context of enantiomer patenting is important and recurring, while also representative of a larger concern in fields such as chemistry, in which the properties of a new product are often known only after it has been made. A large fraction of drugs are made of chiral molecules and the potential for improved effectiveness and lower toxicity in single enantiomer drugs has long been well known. Indeed a 1998 study found that half of a sample of over one thousand drugs under development were single enantiomer drugs.[8] The development of a single enantiomer drug is thus a particularly clear example of an obvious to try research path with unpredictable results: one of two enantiomers will often have more desirable properties, yet testing is required to determine which one and how much more desirable the properties will be.

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[8] *See* Jonathan J. Darrow, *The Patentability of Enantiomers: Implications for the Pharmaceutical Industry*, 2007 Stan. Tech. L. Rev. 2, available at http://stlr.stanford.edu/pdf/darrow-patentability.pdf, for an extensive discussion of the importance of chiral and single enantiomer drugs and their patentability just prior to *KSR*.

We now stand more than two years after this Court issued its opinion in *KSR*. Nevertheless, decisions, such as the one at issue here, continue to turn on a hindsight consideration of unexpected properties rather than on whether, at the time of the invention, the claimed invention was within the grasp of the person of ordinary skill in the art. Federal Circuit case law on the important "obvious to try" issue remains inconsistent, with significant disagreement among the judges. For example, in a case decided while this brief was being written, the majority found a reformulation of an existing drug "obvious to try" over a dissent from the judge who wrote the opinion below in the present case. The majority reasoned that at the time of the invention "a person having ordinary skill in the art ha[d] reached a crossroads where he must choose between two known options," and identified that situation with *KSR*'s "finite number of identified, predictable solutions." *Bayer Schering Pharma AG v. Barr Labs., Inc.*, 2009 U.S. App. LEXIS 17372 (Fed. Cir. August 5, 2009) at *21, *citing KSR*, 550 U.S. at 421.

Now that *KSR* has swept away the categorical rule against "obvious to try" evidence and argument, there is an urgent need for this Court to step in and clarify that post hoc evidence of unexpected results has no role to play in evaluating whether a course of action was sufficiently "obvious to try" to render its results unpatentable under section 103 of the Patent Act.

CONCLUSION

For the foregoing reasons, the petition for writ of certiorari should be granted.

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Respectfully submitted,

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